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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/666,144	Applicant(s) KUMAR ET AL.	
	Examiner J. E. Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-20 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-20, 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 14 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the communication filed on 1/25/08.

The amendment filed 1/25/08 is acknowledged and has been entered.

Claims 14-20, 24-26 are currently pending in the application and are addressed herein.

1. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound having the formula aep PNA II as set forth in claim 14 wherein the compound is a peptide nucleic acid (PNA) and a pharmaceutical composition comprising the compound, does not reasonably provide enablement for the compound having the formula aep PNA II wherein the compound does not comprise a nucleobase. That is, the claims are not enabled for the specifically claimed embodiments that indicate that B is "DNA intercalators" and "heterocyclic moieties" which are non-PNA

embodiments of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The invention is in a class of invention which the CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The claims encompass any compound that meets the structural limitations of formula aep PNA II, as set forth in claim 14. It is noted that the compounds of formula aep PNA II comprise a variable group identified as “B” wherein “each of B is independently selected from the group

consisting of naturally occurring nucleobases adenine (A), thymine (T), cytosine (C) and guanine (G), non-naturally occurring nucleobases, DNA intercalators and heterocyclic moieties”.

Therefore, the claims encompass compounds of formula aep PNA II wherein the compound does not comprise a nucleobase (i.e., the compound is abasic). Furthermore the compound can be only a monomer of the compound of formula aep PNA II or an oligomer comprising up to 20 compounds of formula aep PNA II.

The specification, although it contemplates that the compound wherein each of B is independently selected from the aforementioned group, only discloses the compound as being useful as a peptide nucleic acid (PNA) which hybridizes to complimentary nucleic acid sequences.

The prior art teaches that PNAs are molecules which hybridize to complimentary nucleic acid sequences via hydrogen bonding between a nucleobase of the PNA and the complementary nucleobase of a target nucleic acid. For instance, Ray et al. (FASEB J 2000, vol. 14, pages 1041-1060) teaches, “PNA is capable of sequence-specific recognition of DNA and RNA obeying the Watson-Crick hydrogen bonding scheme, and the hybrid complexes exhibit extraordinary thermal stability and unique ionic strength effects” (see abstract). Ray et al. also teaches:

PNA is still capable of sequence-specific binding to DNA as well as RNA obeying the Watson-Crick hydrogen bonding rules. Its hybrid complexes exhibit extraordinary thermal stability and display unique ionic strength properties. Although PNA was earlier considered primarily a potential drug candidate for gene therapy, today there are three to four major groups of applications for this novel compound. First, it can be used as a molecular tool in molecular biology and biotechnology. Second is its role as lead compound for the development of gene-targeted drugs applying antigene or antisense strategy. Third is the use of PNA for diagnostics purposes and development of biosensors. Fourth, the study of basic chemistry is related to PNA for the improvement of basic architecture, e.g., for supramolecular constructs and to possibly generate a subsequent generation of PNA molecules. (See page 1041, second column).

Therefore, the only potential uses for PNA molecules recognized in the prior art are all based on the ability of the PNA to specifically bind to target nucleic acid via hydrogen bonding between the nucleobases of the PNA molecule and the complementary nucleobases in the target nucleic acid sequence.

The prior art does not appear to recognize any particular use for a PNA molecule that does not comprise a nucleobase. That is, one of skill in the art would not know how to use the claimed compounds which are drawn to the compounds of formula aep PNA II where “B” is not a nucleobase. In other words, the only compounds encompassed by claims 14 and 24 which one of skill in the art would understand how to make and use would be the compounds of formula aep PNA II where “B” is a nucleobase.

The specification only appears to provide guidance and working examples where molecules comprising compounds of formula aep PNA II where “B” is a nucleobase. There is no guidance or working examples demonstrating how to use compounds of formula aep PNA II where “B” is not a nucleobase. The specification indicates that the compound can be used as a probe or as an antisense-type molecule and there does not appear to be any other disclosed use for the claimed compounds. Furthermore, there does not appear to be an indication in the specification nor in the prior art that would demonstrate that an antisense molecule or probe that does not comprise a nucleobase, but which instead comprises a DNA intercalator or a non-nucleobase heterocyclic moiety could be predictably used as a probe or antisense-type molecule.

Considering that the specification and prior art do not indicate what the abasic compounds of formula aep PNA II could be used for, additional experimentation would be required in order to predictably use these particular compounds. The additional

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experimentation would amount to trial-and-error testing of the compound without a guarantee of the outcome. As such, the additional amount of experimentation in order to enable the full breadth of the compounds encompassed by the claim is extremely large.

The level of the skill in the art is deemed to be high.

Considering the nature of the invention, the breadth of the claims, the unpredictable nature of the invention as recognized in the prior art, the limited amount of working examples and guidance provided, and the high degree of skill required to practice the invention, it is concluded that the specification does not provide an enabling disclosure for the instant claims. Therefore, additional experimentation is required before one of skill in the art could make and use the claimed invention to its full scope. The amount of additional experimentation required to perform the broadly claimed invention to its full scope is undue.

Response to Arguments

4. Applicant's arguments filed 1/25/08 have been fully considered but they are not persuasive.

Applicants argue that claim 14 has been amended to exclude compounds wherein B = H, HO, NH₂ or reporter ligands, and thus does not comprise basic sites in aeb PNA II; and thus, amended claim 14 is now directed to a compound having formula aep PNA II, a valid peptide nucleic acid, as it comprises nucleobases. Applicants assert that claim 24, which depends from claim 14, is also so limited. Applicants respectfully submitted that both claim 14 and claim 24 are now free of the rejection.

This is not persuasive because although claim 14 has been amended to remove the indication that B = H, HO, NH₂ or reporter ligands, the claims still explicitly indicate that B = "DNA intercalators" and "heterocyclic moieties". Thus the claims encompass non-PNA embodiments which are not fully enabled for the reasons indicated. For instance, as the only disclosed use of the claimed compounds appears to be for use as a probe or antisense-type molecule which would function by hybridization with target sequences based on base-complementarity, it is unpredictable how the claimed compounds would function as a probe or antisense-type molecule when it does not comprise a nucleobase unit. It is acknowledged that nucleobases as heterocyclic moieties, but the instances encompass non-nucleobase heterocyclic moieties. Therefore, removing the limitations that B = "DNA intercalators" and "heterocyclic moieties" would obviate this rejection.

Allowable Subject Matter

5. Claims 15-20, 25 and 26 are allowed.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
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